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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/591,531	09/01/2006	Frank Pflucker	MERCK-3223	2971

23599 7590 11/27/2009

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EXAMINER	
SULLIVAN, DANIELLE D	
ART UNIT	PAPER NUMBER
1616	

NOTIFICATION DATE	DELIVERY MODE
11/27/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docketing@mwzb.com

Office Action Summary	Application No.	Applicant(s)	
	10/591,531	PFLUCKER ET AL.	
	Examiner	Art Unit	
	DANIELLE SULLIVAN	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 July 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,7-10 and 13-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,7-10 and 13-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application.
6) ☐ Other: _____.

DETAILED ACTION

Claims 1, 2, 7-10 and 13-27 are pending examination on the merits.

Withdrawn rejections

Applicant's amendments and arguments filed 07/06/2009 are acknowledged and have been fully considered. Any rejection and/or objection not specifically addressed below are herein withdrawn. However in view of applicants amendments a new rejection is herein set forth.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 26 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The emulsifier-free emulsion is not clearly disclosed within the specification. The specification states that solutions and emulsions may comprise customary carriers, such as solvents, solubilisers and emulsifiers, for example water, ethanol, isopropanol, oils, polyethylene glycol, etc (page 54, lines 28-32). Therefore, it is difficult to determine what an emulsifier-free emulsion is. Hence, the specification

does not reasonably convey to one skilled in the art what an emulsifier-free emulsion encompasses.

Response to Arguments

Applicant's arguments filed 7/06/2009 have been fully considered but they are not persuasive. Applicants argue that emulsifiers are such as well known to one of ordinary skill in the art and simply stating something is an emulsifier defines it adequately to one of ordinary skill. The Examiner is not persuaded by this argument. The issue is whether the term "emulsifier free emulsion" is indefinite, not the term "emulsifier". The Examiner agrees that the breath of the term "emulsifier can be deciphered, however, the term emulsifier free emulsion cannot because it is unclear what emulsions composition lack the presence of an emulsifier. Hence, it is unclear what is encompassed by the term "emulsifier-free emulsion".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 2, 7-9, 17-20, 22 and 24-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harivel (WO 03/011238) in view of Heger et al. (US 2003/0143166).

Applicant's Invention

Applicant claims encapsulated organic UV filters in powder form, obtained by spray-drying or freeze-drying a dispersion comprising organic UV filters encapsulated by silica gel or silicon dioxide. Claims 7, 8, 20 and 25 further comprise photostabilizers, cosmetics oils and/or antioxidants. Claims 20 and 24 further comprise an additional UV filter selected from octyl methoxycinnamate.

Determination of the scope and the content of the prior art

(MPEP 2141.01)

Harivel teaches aqueous compositions having UV protection properties by the use of UV filters (abstract). UV-B filters include isooctylmethoxycinnamate and other organic filters (page 2, lines 10-12). The hydrophobic UV filters are preferably encapsulated (page 11, lines 21-23). Suitable capsules can have walls made of inorganic polymers, however, preference is given to capsules whose walls are made of silica gel (page 12, lines 4-14). Examples 1-6 all include silica capsules. Preferred capsules have an average particle size in the range from about 10 nm up to about 10000 nm, preferably up to 2000 nm or limited by the application needs (page 12, lines 15-30). All compounds and components used in the cosmetic or pharmaceutical formulations are either known and available commercially or can be synthesized by known processes (page 14, line 35-37).

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

Harivel do not teach the encapsulated UV filters are in powder form obtained by spray-drying or freeze-drying. It is for this reason that Heger et al. is joined.

Heger et al. teaches aqueous dispersions of organic UV filters, which may be encapsulated (abstract; [0015]). In the process for preparing the dispersions the antioxidants and oils (additives) are added before and during the preparation of the dispersion phase [0106]-[1112]. Afterwards, the UV filters are spray-dried or freeze-dried to obtain a powder [0126]. The dry powders obtained no longer lose their properties and the UV filter substance and the core-shell structure is retained [0129]. Claimed also are pulverulent preparations obtained by the process comprising the UV filter substance as nanoparticulate particles in amorphous or partially amorphous form [0130]. The particles have a core/shell structure, where the core comprises the UV filter and the shell comprises at least one protective colloid [0022]. Coating materials include silica [0127]. The formulation may include antioxidants and light stabilizing agents (photostabilizers) to protect the UV filters [0039]. The dispersion preferably has a diameter of less than 500 um [0136].

Finding of prima facie obviousness

Rationale and Motivation (MPEP 2142-2143)

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Harivel and Heger et al. to utilize encapsulate organic UV filters in powder form, obtained by spray-drying or freeze drying encapsulated by silica gel in powder form because Heger et al. teach dry powders

obtained via this method no longer lose their properties and the UV filter substance and the core-shell structure is retained. One of ordinary skill in the art would have been motivated to utilized a known process to improve the properties of the UV filters since the prior art teaches that spray-drying aid in the formulation of stabilized particulate powders.

Claims 1, 10, 13-16 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heger et al. (US 2003/0143166) in view of Harivel (WO 03/011238).

Applicant's Invention

Applicant claims encapsulated organic UV filters in powder form comprising silica gel or silicon dioxide capsules. Applicants claim a process of preparing the UV filters in powder form, comprising spray-drying or freeze-drying a dispersion. Claim 13 specifies the UV filters are in particulate form. Claim 14 limits the size to 10nm to 100nm. Claim 15 specifies that the process may introduce additives before or during the process. Claim 16 specifies the UV filters in powder form are after-treated.

Determination of the scope and the content of the prior art

(MPEP 2141.01)

Heger et al. teaches aqueous dispersions of organic UV filters, which may be encapsulated (abstract; [0015]). In the process for preparing the dispersions the antioxidants and oils (additives) are added before and during the preparation of the dispersion phase [0106]-[1112]. Afterwards, the UV filters are spray-dried or freeze-

dried to obtain a powder [0126]. The particles have a core/shell structure, where the core comprises the UV filter and the shell comprises at least one protective colloid [0022]. Coating materials include silica [0127]. The formulation may include antioxidants and light stabilizing agents (photostabilizers) to protect the UV filters [0039]. The dispersion preferably has a diameter of less than 500 um [0136].

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

Heger et al. do not give exemplify encapsulated organic UV filters with capsules having walls built up of an inorganic material, preferably silica, however, the presence of walls is implied. Heger et al. teach core/shell structures wherein the UV filters are the core and the encapsulated filters are coated by silica. Therefore, it is the Examiners position that Heger et al. teach organic UV filters encapsulated by silica gel, since the UV filters are taught to be encapsulated by at least one protective colloid and coating agents include silica. It is for this reason that Harivel is joined.

Harivel teaches aqueous compositions having UV protection properties by the use of UV filters (abstract). UV-B filters include isooctylmethoxycinnamate and other organic filters (page 2, lines 10-12). The hydrophobic UV filters are preferably encapsulated (page 11, lines 21-23). Suitable capsules can have walls made of inorganic polymers, however preference is given to capsules whose walls are made of silica gel (page 12, lines 4-14). Examples 1-6 all include silica capsules.

Finding of prima facie obviousness

Rationale and Motivation (MPEP 2142-2143)

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Heger et al. and Harivel to encapsulate organic UV filters with an inorganic material, specifically silica. One would have been motivated to encapsulate the UV filters with silica because Harivel teaches organic UV filters that are encapsulated by silica. Since the problem to be solved is the same, the protection of the UV filter compounds, encapsulation of UV filters with silica is prima facie obvious.

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Heger et al. (US 2003/0143166) and Harivel (WO 03/011238) in view of Herzog (US 2003/0235540).

Applicant's Invention

Applicant claims the composition as disclosed above with a self-tanning agent.

Determination of the scope and the content of the prior art

(MPEP 2141.01)

The teachings of Heger et al. and Harivel are disclosed above.

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

Heger et al. and Harivel do not teach the addition of a self-tanning agent. It is for this reason that Herzog is joined.

Herzog teaches that encapsulated UV filters that may include dihydroxyacetone and erythrulose (self-tanning agents) [0003], [0142] and [0205]. The preparations are for cosmetic use may be formulated as skin-tanning preparations [0213].

Finding of prima facie obviousness

Rationale and Motivation (MPEP 2142-2143)

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Heger et al., Harivel and Herzog to utilize a self-tanning agent. One would have been motivated to utilize a self-tanning agent because Herzog teaches that encapsulated UV filters including dihydroxyacetone and erythrulose may be used to obtain self-tanning formulations.

Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Heger et al. (US 2003/0143166) and Harivel (WO 03/011238) in view of Chaudhuri (WO 03/007906).

Applicant's Invention

Applicant claims the composition as disclosed above with at photostabilizer of formula V.

Determination of the scope and the content of the prior art

(MPEP 2141.01)

The teachings of Heger et al. and Harivel are disclosed above.

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

Heger et al. and Harivel do not teach the specific photostabilizer of formula V. It is for this reason that Chaudhuri is joined.

Chaudhuri teaches formula V as a photostabilizer which exhibits antioxidant properties (page 2, lines 25-35).

Finding of prima facie obviousness

Rationale and Motivation (MPEP 2142-2143)

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Heger et al., Harivel and Chaudhuri to utilize he specific photostabilizer of formula V. One would have been motivated to utilize the photostabilizer because Chaudhuri teaches the formula is a photostabilizer which exhibits antioxidant properties.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Danielle Sullivan whose telephone number is (571) 270-3285. The examiner can normally be reached on 7:30 AM - 5:00 PM Mon-Thur EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Patent Examiner
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/Mina Haghighatian/
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